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CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			EXAMINER DOUGHERTY, SEAN PATRICK	
			ART UNIT 4123	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No. 10/587,139	Applicant(s) CHANNER ET AL.	
	Examiner Sean P. Dougherty	Art Unit 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-10 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 21 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>21 July 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is the initial Office action based on the 10/587139 application filed April 5, 2007. Claims 1-10, as originally filed, are currently pending and have been considered below. Claims 1 & 9 are independent.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: ramped inner edge #40. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because: **a)** Fig. 6A & Fig. 6B show the same view of the blood collection device, however part #5 is shaded differently in each view, shading should be identical; **b)** Fig. 1-5, Fig. 6A-B, Fig. 7A-C & Fig. 8 contain solid black shading which is not permitted. (See MPEP § 1.84 (m))

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: **a)** the term "frictional engagement" appears in Claim 10 (Page 10, line 6) and the term definition is not disclosed in the specification. The Examiner notes that the term "frictional engagement" is a definition known to one of ordinary skill in the art, however, has various single definitions; therefore the Applicant has not provided proper antecedent basis for the claimed needle holder that is releasably attached to the housing using frictional engagement (the Examiner is aware that the term "engagement" is disclosed in the specification); **b)** the term "positive

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locking action" appears in Claim 10 (Page 10, line 6) and the term definition is not disclosed in the specification. The Examiner notes that the term "positive locking action" is known to one of ordinary skill in the art, however, has various single definitions; therefore the Applicant has not provided proper antecedent basis for the claimed needle holder that is releasably attached to the housing using positive locking action and by frictional engagement.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner notes the terms "frictional engagement" and "positive locking action" are not disclosed in the specification therefore failing to particularly point and distinctly claim the subject matter which the Applicant regards as the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5 & 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tripp et al. (US 6,186,960 B1).

Regarding claim 1, Tripp et al. discloses a blood collection device comprising:

a housing (tubular body, Fig. 2 #12) having an open rear end adapted to accommodate an evacuated blood collecting tube (collection tube holder, Fig. 2 #12; "inserts an evacuated test tube into the interior of the collection tube holder" Col. 3, lines 7-9) and a front end (distal end, Fig. 2 #32), a needle holder in the front end (needle port hub, Fig. 2 #14), a needle which is attached to the needle holder ("the needle port hub in turn accepts a bi-directional needle" Col. 2, lines 59-60) and which is double ended ("bi-directional needle" Col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing ("one needle end is exposed to the exterior environment and the other needle end is contained within the interior of the collection tube holder" Col. 3 lines 3-6), the needle holder being releasably attached relative to the housing ("detachable needle port hub" Col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted ("needle port hub with affixed needle ... drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), and a needle retraction device (evacuated accessory, Fig. 4 #18), the needle retraction device able to be pushed into the housing ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16) to release the needle holder from the housing and to retract the needle holder containing the attached needle into the needle retraction device ("needle port hub with affixed needle ... drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger

member being deflectable between a locking position where the finger member retains the needle holder to the housing (hub release ring, Fig. 2 #16; "detachable needle port hub is secured within the interior of the collection tube holder at the distal end by a hub release ring that is wedged between the detachable needle port hub and the interior wall of the holder" Col. 2, lines 61-65), and a release position where the needle holder can be retracted into the housing ("the retaining ring holding the combination part within the accessory chamber release[s] from the needle port hub and advance[s] [the needle port hub] into the annular channel" Col. 3, lines 53-55).

Regarding claim 2, Tripp et al. discloses a blood collection device wherein:

the needle holder comprises an assembly of at least two parts, the first part being an inner part (male needle holder, Fig. 2 #46) and containing a passageway through which a puncture needle can extend to fit the puncture needle to the inner part (Fig. 2 discloses a puncture needle [bidirectional needle #48] extending to fit to an inner part [male needle holder #46]), the second part comprising an outer nosepiece (threaded female orifice, Fig. 2 #44), the at least one finger member being attached relative to the nosepiece (Fig. 2 discloses a finger member [hub release ring #16] attached relative to an outer nosepiece [threaded female orifice #48]).

Regarding claim 3, Tripp et al. discloses a blood collection device wherein:

the needle retraction device comprises an elongate hollow body (tubular member, Fig. 4 #30; hollow chamber, Fig. 4 #70) which contains a vacuum ("capable of holding a vacuum" Col. 5, line 34; "the [needle retraction device] has an air release/vacuum seal mechanism that permits the introduction and retention of negative

pressure within the chamber" Col. 3, lines 22-24) and which has an open end (open distal end, Fig. 4 #62), a piston which closes off the open end of the elongate hollow body (combination part, Fig. 4 #20) and which is adapted for sliding movement within the hollow body, and which is releasably attached relative to the open end ("combination part #20 moves[s] axially within tubular member 30" Col. 6, lines 36-37).

Regarding claim 4, Tripp et al. discloses a blood collection device wherein:

the piston comprises at least one finger member (catch ring, Fig. 4 #24; retaining ring, Fig. 4 #28) which releasably attaches the piston relative to the one end of the hollow body, the finger member being movable between a locking position where the piston is attached to the hollow body ("axial force applied to ... evacuated accessory causes the catch ring portion to begin to mate with the detachable needle port hub and affixed needle" Col. 3, lines 43-46), and a release position where the piston can be retracted into the hollow body under the influence of the vacuum ("axial force applied on ... evacuated accessory ... causes retaining ring holding the combination part ... [to be] ... released to the action of the negative pressure ... and the complex is drawn into the interior of the evacuated accessory." Col. 3, lines 51-60).

Regarding claim 5, Tripp et al. discloses a blood collection device wherein:

at least one finger member on the piston extends forwardly from the piston ("axially extending catch ring 24" Col. 6, lines 29-30; retaining ring, Fig. 4 #28), and the at least one finger member on the needle holder extends rearwardly (hub release ring, Fig. 2 #16) such that as the needle retraction device is pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection

tube holder fully" Abstract, lines 15-16), the at least one finger member on the piston releases the at least one finger member on the needle holder, and engages to the at least one finger member on the needle holder ("the catch ring portion of the combination part ... caus[es] the hub release ring holding the needle port hub within the collection tube holder to release from the needle port hub" Col. 3, lines 43-50).

Regarding claim 9, Tripp et al. discloses a blood collection device wherein:
a housing (tubular body, Fig. 2 #12) having an open rear end adapted to accommodate an evacuated blood collecting tube (collection tube holder, Fig. 2 #12; "inserts an evacuated test tube into the interior of the collection tube holder" Col. 3, lines 7-9), and a front end(distal end, Fig. 2 #32), a needle holder in the front end (needle port hub, Fig. 2 #14), a needle which is attached to the needle holder ("the needle port hub in turn accepts a bi-directional needle" Col. 2, lines 59-60) and which is double ended ("bi-directional needle" Col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing ("one needle end is exposed to the exterior environment and the other needle end is contained within the interior of the collection tube holder" Col. 3 lines 3-6), the needle holder being releasably attached relative to the housing ("detachable needle port hub" Col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted ("needle port hub with affixed needle ... drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger member being deflectable between a locking position where the finger

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member retains the needle holder to the housing (hub release ring, Fig. 2 #16; “detachable needle port hub is secured within the interior of the collection tube holder at the distal end by a hub release ring that is wedged between the detachable needle port hub and the interior wall of the holder” Col. 2, lines 61-65), and a release position where the needle holder can be retracted into the housing (“the retaining ring holding the combination part within the accessory chamber release[s] from the needle port hub and advance[s] [the needle port hub] into the annular channel” Col. 3, lines 53-55).

Regarding claim 10, Tripp et al. discloses a blood collection device comprising:

a housing (tubular body, Fig. 2 #12) having an open rear end adapted to accommodate an evacuated blood collecting tube (collection tube holder, Fig. 2 #12; “inserts an evacuated test tube into the interior of the collection tube holder” Col. 3, lines 7-9), and a front end (distal end, Fig. 2 #32), a needle holder in the front end (needle port hub, Fig. 2 #14), a needle which is attached to the needle holder (“the needle port hub in turn accepts a bi-directional needle” Col. 2, lines 59-60) and which is double ended (“bi-directional needle” Col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing (“one needle end is exposed to the exterior environment and the other needle end is contained within the interior of the collection tube holder” Col. 3 lines 3-6), the needle holder being releasably attached relative to the housing (“detachable needle port hub” Col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted (“needle port hub with affixed needle ... drawn into the interior of the evacuated

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accessory" Col. 3 lines 56-60), with the proviso that the needle holder is releasably attached to the housing using a positive locking action and by frictional engagement (hub release ring, Fig. 2 #16; "detachable needle port hub is secured within the interior of the collection tube holder at the distal end by a hub release ring that is wedged between the detachable needle port hub and the interior wall of the holder" Col. 2, lines 61-65). The Examiner notes that the terms "positive locking action" and "frictional engagement" are insufficient absent a disclosure, thus non-limiting.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Kaufhold et al. (US 5,000,736 A).

Regarding claim 6, Tripp et al. discloses a blood collection device wherein:

there is a housing (tubular body, Fig. 2 #12), the housing contacting the at least one finger member on the piston ("operator inserts the evacuated accessory ... pushing completely into the collection tube holder" Col. 3, lines 40-43; the Examiner notes Fig. 6 discloses the one finger member in contact with the housing) when the needle retraction device is pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16), the at least one finger member releases the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum ("the catch ring portion of the combination part ... caus[es] the hub release ring holding the needle port hub within the collection tube holder to release from the needle port hub" Col. 3, lines 43-50).

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the housing is provided a ramp in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

However, ***Kaufhold et al. teaches*** a blood collection device wherein:

the housing is provided a ramp (taper d, Fig. 7) in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

Tripp et al. and Kaufhold et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Kaufhold et al. before him or her to modify the housing of Tripp et al. to include the ramp of Kaufhold et al. The Examiner notes that this is simple substitution of the housing of Tripp et al. to include the ramp of Kaufhold et al. to obtain the predictable result of the at least one finger on the piston to ride along the ramp to release the at least one finger member from the engagement with the hollow body to enable the piston to retract into

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the hollow body. The Examiner notes that the finger as disclosed in Tripp et al. already rides along the housing of Tripp et al. to engage and release the piston into the hollow body; adding the ramp as taught in Kaufhold et al. simply modifies the housing of Tripp et al., obtaining the same result of the release of the piston into the hollow body. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (Col. 3, lines 65-67) as disclosed by Tripp et al., to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to "provid[e] a means of automatically, without the need of unusual manipulation, rendering a used syringe safe for handling immediately after use" (Col. 1, lines 65-67) as taught by Kaufhold et al. Therefore, it would have been obvious to combine Tripp et al. with Kaufhold et al. to obtain the invention in the instant claim 6.

14. Claim 7 is is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Daley et al. (US 6,572,565 B2).

Regarding claim 7, Tripp et al. discloses a blood collection device wherein:

a piston (combination part, Fig. 4 #20) and a needle retraction device (evacuated accessory, Fig. 4 #18) that are pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16).

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle.

However, ***Daley et al. teaches*** a blood collection device wherein:

the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle ("The vial is inserted into the extractor end of the cylinder 10 so that the posterior end 30 of the needle 26 pierces through a stopper or membrane in the vial" Col. 5, lines 31-34; Fig. 2 discloses the inner end of the needle [posterior end] #30 sealed by the pierceable material [stopper] #66).

Tripp et al. and Daley et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Daley et al. before him or her to modify the piston of Tripp et al. to include the pierceable material of Daley et al. The Examiner notes that the combination of the piston and the pierceable member is simply combining prior art elements according to known methods to yield predictable results. The Examiner additionally notes that this is applying a known technique to a known device ready for improvement to yield predictable results. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the piston disclosed by Tripp et al. by adding the pierceable member taught by Daley et al. to be pierced by the inner end of the needle when the needle retraction

device is pushed against the rear of the needle holder to seal the inner end of the needle. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (Col. 3, lines 65-67) as disclosed by Tripp et al., to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to "provide an improved blood sampling assembly for retracting a needle and needle seat from a cylinder and thereby shielding the needle after completion of a blood collection procedure" (Col. 3, lines 44-47) as taught by Daley et al. Therefore, it would have been obvious to combine Tripp et al. with Daley et al. to obtain the invention in the instant claim 7.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Vallenlunga et al. (US 5,352,203 A).

Regarding claim 8, Tripp et al. discloses a blood collection device comprising: a piston (combination part, Fig. 4 #20) that retracts into a hollow body ("combination part #20 moves[s] axially within tubular member 30" Col. 6, lines 36-37) .

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body.

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However, Vallenglunga et al. teaches a blood collection device wherein:
the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body ("The second connecting member includes a plurality of protrusions 28 which extend radially away from a second aperture 27 to form a friction fit within the inner diameter of an outer housing" Col. 4, lines 10-14).

Tripp et al. and Vallenlunga et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Vallenlunga et al. before him or her to modify the plunger of Tripp et al. to include the sealing members extending from the piston and sealing engaging with the hollow body providing a friction force of Vallenlunga et al. The Examiner notes that the combination of the piston and the sealing members is simply combining prior art elements according to known methods to yield predictable results. The Examiner additionally notes that this is use of a known technique to improve similar devices in the same way. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the plunger to include sealing members along the walls to provide friction. It is known to one of ordinary skill in the art that a plurality of protrusions along the plunger to form a friction fit with an inner diameter would obtain the predictable result of creating friction acting as a speed controller. The suggestion/motivation for doing so would have been to

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“provide a disposable medical collection tube holder with retractable needle” (Col. 3, lines 65-67) as disclosed by Tripp et al., to “provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory” (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to a “plunger for a non-reusable syringe ... capable of aspirating fluids” (Col. 1, lines 5-9) and to provide “a non-reuseable syringe which becomes inoperative or incapable of further use automatically without an additional act on the part of the user” (Col. 1, lines 42-45) as disclosed by Vallenlunga et al. Therefore, it would have been obvious to combine Tripp et al. with Vallenlunga et al. to obtain the invention in the instant claim 8.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean P. Dougherty whose telephone number is (571) 270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SPD


JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER
10/3/07